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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,674	03/23/2001	Beat Muller	CL/V-31362A	5772

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THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

WILSON, DONALD R

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 08/21/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,674

Applicant(s)

MULLER ET AL.

Examiner

Donald R Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed 7/25/03, has been fully considered with the following results.
2. The amendment is not deemed to be persuasive in overcoming the rejection under 35 U.S.C. § 112, first paragraph, and the rejection is maintained for reasons discussed below.
3. The rejection under 35 U.S.C. § 112, second paragraph, concerning the use of the term "obtainable", and the improper Markush language of Claim 3 are overcome by the amendment and in these regards the rejection is withdrawn. However, the other bases of rejection under 35 U.S.C. § 112, second paragraph, are maintained for reasons discussed below.
4. The amendment overcomes the prior art rejections which are withdrawn.
5. The objection to the title is withdrawn.

Previously Cited Statutes

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112, First Paragraph

7. **Claims 1-3 and 5-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prepolymers, wherein the chain transfer reagent has a functional group in addition to the chain transfer group, and wherein said functional group is then converted to a group having ethylenic unsaturation by reaction with a compound having an ethylenically unsaturated group, does not reasonably provide enablement for prepolymers wherein the chain transfer agent does not have such groups, and wherein the reaction in step (b) does not result in attachment of an ethylenically unsaturated group to the prepolymer.** The basis of this rejection was stated in Detailed Action § 5 of the previous Office Action. Applicant traverses the rejection arguing that the claims have been amended to specify the functional groups of the chain transfer agent comprised in the resulting copolymer. This is not deemed to be persuasive because (i) the group

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responsible for the chain transfer is itself a functional group, and (ii) reaction with a compound having an ethylenically unsaturated group will not provide the inventive compositions unless the reaction with said functional group is other than with said unsaturated group. Applicants have asked for an example of language which would overcome the rejection. An example would be in step (a) to recite "--- in the presence of a chain transfer agent, which in addition to the chain transfer group contains a functionality reactive with the organic compound of step (b)", and in step (b) to recite "reacting an organic compound having an ethylenically unsaturated group and a group which reacts with said functionality introduced by the chain transfer agent in step (a)". It is also not seen that there is any teaching for the currently recited "one or more" functional groups.

Claim Rejections - 35 USC § 112, Second Paragraph

8. ***Claims 1-3 and 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*** The basis of this rejection was stated in Detailed Action § 9-10 of the previous Office Action.

9. The language of Claim 1 is indefinite because "hydrophilic" is a relative term the metes and bounds of which cannot be determined. Applicant's amendment inserting that the hydrophilic monomer gives as a homopolymer, a polymer which is water-soluble or can absorb at least 10% by weight of water is not deemed to overcome the basis for the rejection. One of ordinary skill in the art would not know what percent solubility is necessary, or under what conditions solubility or water uptake is to be measured. The statement that "---one of ordinary skill in the art would understand the metes and bounds of this definition as used in the biomedical device industry", is not deemed to be persuasive because it is not supported with any evidence.

10. The language of Claim 2 is unclear because of the number of nested Markush groups, some of which are in the wrong form, and the inconsistent punctuation, concerning the definition of R₃.

¹ The "typo" in the stated rejection of the previous Office Action ("9" being missing) is acknowledged. It is appreciated that applicant recognized this inadvertent error by acknowledging the rejection as correctly being of Claims 1-9.

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The claim needs to be rewritten using proper Markush language and making the nesting of groups clear by the use of indentation and/or punctuation. Applicant's amendment to Claim 2 does not overcome the rejection, which might have been solved by adhering to the format set forth in MPEP § 2173.05(h), which was previously referenced. First, it is pointed out that "wherein R is a material selected from the group consisting of A, B, C or D", or alternatively, "wherein R is A, B, C and D" are not acceptable formats. Secondly, a Markush group is a closed group and only the last member of a group should be separated by "or" or "and" as is appropriate to the form being used. This is particularly true where applicant has used nested group of mixed styles. Finally, indentation of the sub groups would have permitted a clearer understanding of the nested Markush groups in the claim. An example would be as follows:

---R₃ is

- i. A selected from the group consisting of
 - (1) D selected from the group consisting of:
 - (a) G, and
 - (b) H
 - (2) E, and
 - (3) F wherein F is
 - (c) I, or
 - (d) J,
- ii. B,
- iii. C, or
- iv. D."

Currently the last member of the various groups can not be told because "and" is missing in the selected from the group consisting of format, and "or" appears to be used to separate more than just the last member in the other format. It is also noted that if the semi colons are intended to separate the members of the first nested Markush group, then at least some members of the group would clearly not be enabled, e.g., R₃ being "a radical -OY₃, wherein Y₃ is hydrogen" indicates a non-existent monomer (vinyl alcohol)

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for the indicated polymerization, and R_3 being C_1 - C_4 -alkyl would clearly not be a hydrophilic monomer by any definition.

Action Is Final

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. This application contains claims 10-14 are drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald R Wilson whose telephone number is 703-308-2398.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 703-308-2450. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. The unofficial direct fax phone number to the Examiner's desk is 703-872-9029.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-2351.



Donald R Wilson
Primary Examiner
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